

- 2.) Claims 2, 6 and 10, drawn to a *Streptococcus pneumoniae* protein or polypeptide of Table 2 or a fragment thereof, classified in class 530, subclass 350.
- 3.) Claims 6 and 10, drawn to a fragment of a *Streptococcus pneumoniae* protein or polypeptide of Table 3, classified in class 530, subclass 300.
- 4.) Claims 7 and 13, drawn to a DNA sequence set out in Table 1, classified in class 536, subclass 23.7.
- 5.) Claims 8 and 13, drawn to a DNA sequence set out in Table 2, classified in class 536, subclass 23.7.
- 6.) Claim 13, drawn to a nucleic acid sequence defined in Table 3, classified in class 536, subclass 23.7.
- 7.) Claim 15, drawn to an antibody capable of binding to a protein or polypeptide as defined in Table 1, classified in class 530, subclass 387.9.
- 8.) Claim 15, drawn to an antibody capable of binding to a protein or polypeptide as defined in Table 2, classified in class 530, subclass 387.9.
- 9.) Claim 15, drawn to an antibody capable of binding to a protein or polypeptide as defined in Table 3, classified in class 530, subclass 387.9.
- 10.) Claim 9, drawn to a method of use of a protein or polypeptide of *Streptococcus pneumoniae* shown in Table 1, classified in class 436, subclass 543.
- 11.) Claim 9, drawn to a method of use of a protein or polypeptide of *Streptococcus pneumoniae* shown in Table 2, classified in class 436, subclass 543.
- 12.) Claim 9, drawn to a method of use of a protein or polypeptide of *Streptococcus pneumoniae* shown in Table 3, classified in class 436, subclass 543.
- 13.) Claim 14, drawn to a method of detection of *S. pneumoniae* using a protein or polypeptide as defined in Table 1, classified in class 435, subclass 7.2.
- 14.) Claim 14, drawn to a method of detection of *S. pneumoniae* using a protein or polypeptide as defined in Table 2, classified in class 435, subclass 7.2.
- 15.) Claim 14, drawn to a method of detection of *S. pneumoniae* using a protein or polypeptide as defined in Table 3, classified in class 435, subclass 7.2.
- 16.) Claim 17, drawn to a method of detection of *S. pneumoniae* using an antibody to a protein or polypeptide as defined in Table 1, classified in class 435, subclass 7.1.
- 17.) Claim 17, drawn to a method of detection of *S. pneumoniae* using an antibody to a protein or polypeptide as defined in Table 2, classified in class 435, subclass 7.1.
- 18.) Claim 17, drawn to a method of detection of *S. pneumoniae* using an antibody to a protein or polypeptide as defined in Table 3, classified in class 435, subclass 7.1.
- 19.) Claim 18, drawn to a method of detection of *S. pneumoniae* using a nucleic acid as defined in Table 1, classified in class 435, subclass 6.
- 20.) Claim 18, drawn to a method of detection of *S. pneumoniae* using a nucleic acid as defined in Table 2, classified in class 435, subclass 6.
- 21.) Claim 19, drawn to a method of inactivating a protein or polypeptide shown in Table 1, classified in class 530, subclass 427.
- 22.) Claim 19, drawn to a method of inactivating a protein or polypeptide shown in Table 2, classified in class 530, subclass 427.

- 23.) Claim 19, drawn to a method of inactivating a protein or polypeptide shown in Table 3, classified in class 530, subclass 427.
- 24.) Claim 20, drawn to a method of use of an agent capable of antagonizing the function of a protein or polypeptide shown in Table 1, classified in class 435, subclass 961.
- 25.) Claim 20, drawn to a method of use of an agent capable of antagonizing the function of a protein or polypeptide shown in Table 2, classified in class 435, subclass 961.
- 26.) Claim 20, drawn to a method of use of an agent capable or antagonizing the function of a protein or polypeptide shown in Table 3, classified in class 435, subclass 961."

See Paper No. 15, pages 2-4. The Examiner further required election of one sequence falling within one of the above-identified inventions.

Applicants respectfully traverse this restriction requirement on the grounds set forth *infra*.

According to M.P.E.P. § 803, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. See MPEP § 803 (emphasis added). In the instant case an examination of claims directed to nucleotide sequences, protein sequences encoded by the same nucleotide sequences, and antibodies that bind to the recited protein sequences, does not present a search creating an undue burden on the Examiner. The art can be searched for nucleic acids, proteins and polypeptides encoded by those nucleic acids, and antibodies that bind to the proteins, as each of these groups is related to the other by the nature of the invention. Therefore, a search of one of these restricted inventions will often result in references disclosing the other inventions as well. For example, it is common in scientific publications disclosing novel expressed nucleotide sequences to additionally disclose the corresponding amino acid sequence(s), as well as antibodies that bind to those amino acid sequences (for example for protein purification purposes).

Applicants' traversal is further supported by a review of the International Search Report for International Application Number PCT/GB99/02452 (attached herewith as Appendix A). The instant application was filed as a Continuation application of International Application Number PCT/GB99/02452. The International Search Report identifies multiple inventions in the international application. However, a review of the inventions 1-87 reveals that each of these inventions is characterized by nucleotide sequences, protein and

polypeptide sequences encoded by those nucleotide sequences and antibodies directed to said protein or polypeptides, among others. For example, a lack of unity of invention was *not* found between “a *Streptococcus pneumoniae* protein or polypeptide having a sequence as depicted in SeqIdNo.2...a nucleic acid molecule encoding for the same or a homologue, derivative or fragment of said protein or polypeptide...[and] an antibody to said protein or polypeptide.” See International Search Report, characterization of “Invention 1” under Observations where unity of invention is lacking. Instead, a lack of Unity was found between each of Inventions 1-87 as well as the subject matter of claim 20. Under PCT Rule 13.2, Unity of Invention shall be fulfilled between a group of claimed inventions “when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” See Patent Cooperation Treaty, Rule 13.

Applicants assert that the special technical relationship between a DNA sequence and a protein or polypeptide sequence encoded by the same DNA sequence is such that a search of these restricted inventions does not create an undue burden on the Examiner. For example, it is a matter of routine to deduce a protein sequence encoded by a DNA sequence once the DNA sequence is known. Utilizing the DNA sequence, protein sequences available in databases can easily be searched using local alignment search tools such as BLAST. Therefore, at a minimum Applicants assert that restriction between DNA sequences and proteins encoded by those DNA sequences does not impose an undue burden on the Examiner. Applicants respectfully request reconsideration and withdrawal of the restriction requirement at least as between DNA sequences provided in Tables 1 and 2, and the protein sequences encoded by those DNA sequences, and provided in Tables 1 and 2.

In the event that the restriction requirement is made final, and in order to fully comply with the response requirements as set forth in 37 C.F.R. § 1.143 (2002), Applicants hereby provisionally elect the invention of group two (2), represented by claims 2, 6 and 10, drawn to a *Streptococcus pneumoniae* protein or polypeptide of Table 2 or a fragment thereof, classified in class 530, subclass 350. Applicants hereby further provisionally elect the following protein sequence from Table 2, falling within the provisionally elected invention of group two (2):

MGIALENVNFTYQEGTPLASAALSDVSLTIEDGSY TALIGHTGSGKSTILQLLN
 GLLVPSQGSVRVFDLITSTSKNKDIRQIRKQVGLVFQFAENQIFEETVLKDVAFGPQ
 NFGVSEEDAVKTAREKLALVGIDESLFDRSPFELSGGQMRRVAIAGILAMEPAILVLD

EPTAGLDPLGRKELMTLFFKKLHQSGMTIVLVTHLMDDVAEYANQVYVMEKGRLVK
GGKPSDVFQDVVFMEEVQLGVPKITAFCKRLADRGVSFKRLPIKIEEFKESLNG

Applicants further hold the remaining claims (corresponding to Groups 1 and 3 - 26) in abeyance under the provisions of 37 CFR § 1.142(b) until final disposition of the elected claims.


Conclusion

Applicants believe that consideration of the above remarks have placed this application in a condition for allowance. Early notification of a favorable consideration is respectfully requested.

Dated: February 4, 2003

Respectfully submitted,

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Appendix A

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International Bureau



(43) International Publication Date
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PCT

(10) International Publication Number
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(51) International Patent Classification⁷: **C12N 15/31**,
C07K 14/315, 16/12, A61K 31/70, 39/09, G01N 33/53,
33/68, C12Q 1/68

(21) International Application Number: PCT/GB99/02452

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60/125,329 19 March 1999 (19.03.1999) US

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(81) Designated States (*national*): CN, JP, US.

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Published:

— with international search report

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23 August 2001

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.



WO 00/06738 A3

(54) Title: NUCLEIC ACIDS AND PROTEINS FROM *STREPTOCOCCUS PNEUMONIAE*

(57) Abstract: Novel proteins from *Streptococcus pneumoniae* are described, together with nucleic acid sequences encoding them. Their use in vaccines and in screening methods is also described.

INTERNATIONAL SEARCH REPORT

International Application No

PC1, GB 99/02452

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/31 C07K14/315 C07K16/12 A61K31/70 A61K39/09
G01N33/53 G01N33/68 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K A61K G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 95 06732 A (MASURE H ROBERT ;TUOMANEN ELAINE (US); PEARCE BARBARA J (US); UNIV) 9 March 1995 (1995-03-09) SeqIdNo.45: 100.0% identity in 52 aa overlap with SeqIdNo.2 -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: R70181, 15 February 1996 (1996-02-15) MASURE H ET AL: "SPRU37 signal sequence" XP002125470 100.0% identity in 52 aa overlap with SeqIdNo.2 abstract</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	4-7,9-19



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

15 March 2000

Date of mailing of the international search report

04.04.00

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Authorized officer

Lonnoy, 0

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/02452

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 98 18931 A (DOUGHERTY BRIAN A ;HUMAN GENOME SCIENCES INC (US); ROSEN CRAIG A () 7 May 1998 (1998-05-07) -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: V52163, 23 October 1998 (1998-10-23) BARASH S ET AL: "Streptococcus pneumoniae genome fragment SeqIdNo.30" XP002125471 SeqIdNo.30 of W09818931: 100.0% identity in 1200 bp overlap with SeqIdNo.1 abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: V52256, 23 November 1998 (1998-11-23) BARASH S ET AL: "Streptococcus pneumoniae genome fragment SeqIdNo.123" XP002133080 SeqIdNo.123 of W09818931: 100.0% identity in 729 bp overlap with SeqIdNo.71 abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: V52225, 23 October 1998 (1998-10-23) BARASH S ET AL : "Streptococcus pneumoniae genome fragment SeqIdNo.92" XP002133081 SeqIdNo.92: 100.0% identity in 759 bp overlap with SeqIdNo.95 abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: V52191, 23 October 1998 (1998-10-23) BARASH S ET AL: "Streptococcus pneumoniae genome fragment SeqIdNo.58" XP002133082 SeqIdNo.58 of W09818931: 100.0% identity in 1071 bp overlap with SeqIdNo.101 abstract</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	1-19

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/02452

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 97 37026 A (KNOWLES DAVID JUSTIN CHARLES ;SMITHKLINE BEECHAM PLC (GB); HODGSON) 9 October 1997 (1997-10-09) claims 17,20 -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: X30910, 20 May 1999 (1999-05-20) BLACK M ET AL: "Streptococcus pneumoniae genomic DNA sequence SEQ ID NO:187" XP002125472 SeqIdNo.187 of W09737026: 96.5% identity in 259 bp overlap abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: Y11194, 20 May 1999 (1999-05-20) BLACK M ET AL: "S. pneumoniae sulfate transport ATP-binding protein" XP002133083 SeqIdNo.304 of W09737026: 96.7% identity in 242 aa overlap with SeqIdNo.72 / SeqIdNo.65 of W09737026: 98.2% identity in 729 bp overlap with SeqIdNo.71 abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: Y11157, 20 May 1999 (1999-05-20) BLACK M ET AL: "S. pneumoniae triosephosphate isomerase" XP002133084 SeqIdNo.267: 100.0% identity in 131 aa overlap with SeqIdNo.96 / SeqIdNo.35: 97.6% identity in 760 bp overlap with SeqIdNo.95 abstract</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	1-19

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/02452

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 97 43303 A (NICHOLAS RICHARD OAKLEY ;KNOWLES DAVID JUSTIN CHARLES (GB); HODGSO) 20 November 1997 (1997-11-20) -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: W38539, 6 November 1998 (1998-11-06) BLACK M ET AL: "S. pneumoniae sulphate transport ATP-binding protein" XP002133085 SeqIdNo.335: 99.3% identity in 148 aa overlap with SeqIdNo.72 / SeqIdNo.62: 97.0% identity in 732 bp overlap with SeqIdNo.71 abstract -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: W38637, 9 November 1998 (1998-11-09) BLACK M ET AL: "S. pneumoniae triosephosphate isomerase" XP002133086 SeqIdNo.434: 98.9% identity in 179 aa overlap with SeqIdNo.96 / SeqIdNo.149: 97.8% identity in 760 bp overlap with SeqIdNo.95 abstract</p> <p style="text-align: center;">---</p>	1-19
X	<p>WO 98 26072 A (BURGETT STANLEY G ;JASKUNAS STANLEY R JR (US); NORRIS FRANKLIN H () 18 June 1998 (1998-06-18) -& DATABASE GENESEQ E.M.B.L. Databases Accession Number: W80631, 24 December 1998 (1998-12-24) BALTZ R ET AL: "S. pneumoniae putrescine transport system permease protein" XP002133087 98.3% identity in 58 aa overlap with SeqIdNo.102 abstract</p> <p style="text-align: center;">---</p>	1-19
A	<p>POQUET I ET AL: "An export-specific reporter designed for gram-positive bacteria: application to Lactococcus lactis" J. BACTERIOL., vol. 180, no. 7, April 1998 (1998-04), pages 1904-1912, XP002125469 cited in the application</p> <p style="text-align: center;">---</p>	
A	<p>WO 98 31786 A (LE PAGE RICHARD WILLIAM FALLA ;WELLS JEREMY MARK (GB); GILBERT CHR) 23 July 1998 (1998-07-23) -----</p>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/02452

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 20
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
1-19 (all partially), as relating to inventions 1, 36, 48 and 51

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Invention 1: claims 1-19 (all partially)
A Streptococcus pneumoniae protein or polypeptide having a sequence as depicted in SeqIdNo.2; a homologue or derivative of said protein or polypeptide; an antigenic and/or immunogenic fragment of said protein or polypeptide; a nucleic acid molecule comprising or consisting of SeqIdNo.1, a nucleic acid molecule complementary to said sequence, a nucleic acid molecule encoding for the same or a homologue, derivative or fragment of said protein or polypeptide; use of said protein or polypeptide as an immunogen and/or an antigen; an immunogenic composition and/or antigenic composition comprising said protein or polypeptide; an antibody to said protein or polypeptide; a method of detection/diagnosis of S.pneumoniae comprising said protein or polypeptide, said antibody, or said nucleic acid molecule; a method of determining whether said protein or polypeptide represents a potential antimicrobial target which comprises inactivating said protein or polypeptide and determining whether S.pneumoniae is still viable.

2. Inventions 2-87: claims 1-19 (all partially)
Idem as subject 1 but limited to each of the polynucleotide and polypeptide sequences as in SeqIdNo:3-170, SeqIdNo:195 and SeqIdNo:196, wherein invention 2 is limited to SeqIdNo:3 and SeqIdNo:4, invention 3 is limited to SeqIdNo:5 and SeqIdNo:6, ..., invention 85 is limited to SeqIdNo:169 and 170, invention 86 is limited to SeqIdNo:195, and invention 87 is limited to SeqIdNo:196.

For the sake of conciseness, the first subject-matter is explicitly defined, the other subject-matters are defined by analogy thereto.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 20

Present claim 20 relates to the use of an agent defined by reference to a desirable characteristic or property, namely an agent capable of antagonising, inhibiting or otherwise interfering with the function or expression of a protein or polypeptide as defined in Tables 1-3.

The claims cover all agents having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for none of such agents. In the present case, the claim so lacks support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claim also lacks clarity (Article 6 PCT). An attempt is made to define the agent by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, no search can be carried out for such speculative claim the wording of which is in fact a mere recitation of the results to be achieved.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 99/02452

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